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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/732,782	12/10/2003	Stephen Hsu	275.0007 0101	6883

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MUETING, RAASCH & GEBHARDT, P.A.
P.O. BOX 581415
MINNEAPOLIS, MN 55458

EXAMINER

JOYCE, CATHERINE

ART UNIT	PAPER NUMBER
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1642

MAIL DATE	DELIVERY MODE
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05/17/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/732,782

Applicant(s)

HSU ET AL.

Examiner

Catherine M. Joyce

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 February 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11, 17, 25, 26, 33 and 36 is/are pending in the application.
- 4a) Of the above claim(s) 1, 7-9 and 36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-6, 10, 11, 17, 25, 26 and 33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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1. The Amendment filed March 3, 2006 in response to the Office Action of December 7, 2005 is acknowledged and has been entered. Claims 1-11, 17, 25, 26, 33 and 36 are pending, claims 1, 7-9 and 36 are withdrawn from consideration as being drawn to a non-elected invention, and claims 2-6, 10, 11, 17, 25, 26 and 33 are being examined.
2. New claim 36 is a distinct method with differing objectives and method steps from the claims currently being considered. Since applicant has received an action on the merits for the originally presented invention, claim 36 is withdrawn from consideration as being directed to a non-elected invention. See 37 C.F.R. 1.142(b) and M.P.E.P. 821.03.
3. The following rejections are being maintained:

Claim Rejections - 35 USC 112

4. Claims 2-6, 10, 11, 17, 25, 26, and 33 remain rejected under 35 USC 112, second paragraph, for the reasons set forth previously in the Paper mailed October 18, 2006, Section 14, pages 7-12.

Applicant argues that the term "higher p57/KIP2 level" in claim 10 " is defined by the claim and is well understood to one of skill of in the art. In particular, Applicant argues that with the method of claim 10 one (i) determines the p57/KIP2 level in the normal cells, (ii) determines the p57/KIP2 level in the cancer cells, and (iii) compares the p57/KIP2 level in the normal cells to the p57/KIP2 level in the cancer cells after contacting with the agent, wherein a higher p57/KIP2 level in the normal cells compared to the p57/KIP2 level in the cancer cells indicates the agent is effective for the treatment of cancer.

Applicant's arguments have been considered but have not been found to be persuasive. Although one of skill in the art would be able to understand the words "higher p57/KIP2 level", one of skill in the art would not know the metes and bounds of

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the claims because one of skill in the art would not know what degree of "higher p57/KIP2 level" would allow one of skill in the art to determine that a test agent is effective for the treatment of cancer. In particular, one of skill in the art would recognize that any two samples are not likely to give exactly the same result when measured for any particular analyte level, and thus any two samples are likely to have at least a de minimis difference in a level of expression whether or not the test agent is effective for the treatment of cancer. Thus, one of skill in the art would not be apprised of what level of difference in p57/KIP2 level is likely to indicate an agent as effective in the treatment of cancer, and thus one of skill in the art would not be reasonably apprised of the scope of the invention.

5. Claims 2-6, 10, 11, 17, 25, 26, and 33 remain rejected under 35 USC 112, first paragraph, for the reasons set forth previously in the Paper mailed October 18, 2006, Section 14, pages 7-12.

Applicant argues that the specification presents adequate guidance, including working examples, to allow one of skill in the art to practice the claimed invention without undue experimentation. In particular, Applicant argues that the specification presents working examples using the claimed method to identify at least three agents (green tea, GTPP and EGCG) that are effective for the treatment of cancer (citing the specification at page 31, lines 26-29; page 34, lines 8-11; page 36, lines 1-10; page 40, lines 12-18; and page 71, lines 26-28). Applicants further argue that Katiyar and Elmets (International Journal of Oncology 18:1307-1313, 2001), Stoner and Mukhtar (Journal of Cellular Biochemistry, Supplement 22:169-180, 1995), and Suganuma et al. (Mutation Research 428:339-344, 1999) (copies provided with the Information Disclosure Statement filed August 12, 2004), which demonstrate the in vivo therapeutic effectiveness of green tea, GTPP, and EGCG in cancer. In particular, Applicant cites the following quotation from the above cited references: "a case-control study on breast cancer patients revealed high daily consumption of green tea was associated with a lower recurrence rate among Stages I and II patients" (see Suganuma et al, abstract);

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"anticarcinogenic effects of green tea are mainly determined in various animal models," "oral feeding of GTP to... mice resulted in significant protection against skin mmorogenesis when evaluated in terms of tumor incidence, tumor multiplicity and tumor size," "topical application of ECGC inhibited photocarcinogenesis in... mice with no visible toxicity," and "the water extract of green tea as a sole source of drinking water to mice afforded protection against UVB radiation induces tumor initiation and tumor promotion and also induced partial regression of established skin papillomas" (see Katiyar and Elmets, page 1309); and GTPs and ECGC "possess strong anticarcinogenic effects in skin and other tissue" (see Stoner and Mukhtar, page 170 and 172). Applicants further argue that the relevance of the statement that "one cannot extrapolate the teachings of the specification to the enablement of the claims because the finding that green tea polyphenols induce a p57/KIP2 response in normal cells but not in cancer cell lines, is not sufficient to establish that such a differential effect occurs in vivo" (page 6, Office Action mailed October 18, 2006) is not understood because Applicants are not claiming a method of treating a subject with cancer by administering an agent that induces the differential indction of p57/KIP2 in normal versus cancer cells.

Applicant's arguments have been considered but have not been found to be persuasive. In particular, Applicant's argument appears to be that because the specification demonstrates that the green tea polyphenol compound ECGC meets the limitations of the claim and because the art teaches that green tea, particularly ECGC, is associated with anti-cancer effects, compounds identified via the claimed method would necessarily be effective for the treatment of cancer. This argument has been considered but has not been found to be persuasive because, as set forth in the previous Office Action, cancer treatment is known to be unpredictable and many agents that have activity in vitro activity, even anti-cancer cytotoxic activity in vitro, have been found not to be efficacious in the treatment of cancer. Further, the claimed method has not been employed to identify any agents that effective in the treatment of cancer because the only agent tested via the claimed method was previously known to be

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effective in the treatment of cancer. Thus, a correlation between in vitro activity in accordance with the claims and anti-cancer effectiveness cannot be assumed and cannot be predicted. Applicants arguments that a method of treating a subject with cancer is not being claimed are not found to be persuasive because applicants are claiming a method of identifying an agent that is effective for treatment of cancer, and thus in the absence of the predictable treatment of cancer with agents identified by the claimed method the claims are not enabled.

6. No claims are allowed.

7. Applicant's amendment necessitated the new grounds of rejection.

Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine M. Joyce whose telephone number is 571-272-3321. The examiner can normally be reached on Monday thru Friday, 10:15 - 6:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley, can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8700.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Catherine M. Joyce
Examiner
Art Unit 1642



SHANON FOLEY
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600